

**REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and specification and the following remarks.

***Status of the Claims***

In the present Amendment, claims 1 and 13 have been amended. Also, claims 6 and 15 have been cancelled, and claims 4, 5 and 12 were previously cancelled, without prejudice or disclaimer of the subject matter contained therein. Further, claims 21-24 have been added. Thus, claims 1-3, 7-11, 13, 14 and 16-24 are pending in the present application.

No new matter has been added by way of these amendments. The subject matter of claim 6 has been incorporated into claim 1. Also, the subject matter of claim 15 has been incorporated into claim 13. New claims 21-24 have support in the specification at page 8, last paragraph (or paragraph [0049] of U.S. 2005/0234558)

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

***Issues under 35 U.S.C. § 102(b)***

Claims 1, 2, 11, 13, 14 and 17-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Leitao (U.S. Patent No. 6,069,295; hereinafter "Leitao '295") (see paragraphs 2-3 of the Office Action). Applicants respectfully traverse, and reconsideration and withdrawal of

this rejection are respectfully requested. Applicants note that claims 1 and 13 are independent claims, and are thus discussed separately below.

Instantly Pending Claim 1 and Claims Dependent Thereon

Applicants respectfully refer the Examiner to claim 1 as shown herein. In this regard, this rejection has been instantly overcome as the subject matter of claim 6 is not at issue. Thus, withdrawal of this rejection is respectfully requested. Applicants add the following points of distinction.

As amended, claim 1 is directed to a desired microroughness being provided by treating the metallic implant surface with an aqueous solution of hydrofluoric acid, wherein the concentration of the hydrofluoric acid is less than 0.5 M. In contrast to the present invention, the cited Leitao '295 reference discloses an implantable device, a process of producing such a device and the biomedical use of such a device, wherein the surface roughness is said to be a critical factor in Leitao '295 (see column 1, lines 44-45). In column 2, lines 42-55 of Leitao '295, several mechanical surface treatments are exemplified which may be used to obtain a surface roughness, wherein treatment with hydrofluoric acid is one of the mentioned treatments. In relation to this, it is mentioned that "it is important that the surface roughness is performed under controlled conditions to ensure a uniform result" (see the Leitao '295 specification at column 2, lines 55-57). However, Leitao '295 remains silent on the meaning of such "controlled conditions" and does not disclose all instantly claimed features.

In particular, in the present invention, in order to obtain a surface roughness comprising pores and peaks having a diameter of  $\leq 1 \mu\text{m}$ , a pore depth of  $\leq 500 \text{ nm}$ , and a peak width, at half

the pore depth, of from 15 to 150% of the pore diameter, which has been shown to give surprisingly good biocompatibility results (see paragraph [0021] of the present published application), the concentration of the hydrofluoric acid should be less than 0.5 M. The concentration of HF (aq) determines the ratio between etched areas; i.e., areas having a microroughness, and non-etched areas (paragraph [0063]). Regarding the surprising results, the present invention achieves both an improved rate of attachment and a stronger bond between the implant surface and bone tissue. Leitao '295 gives no guidance or disclosure to one of ordinary skill in the art on how to achieve the instantly claimed hydrofluoric acid concentration as well as the advantages of the present invention.

Put differently, Leitao '295 fails to disclose any details of a method wherein a surface roughness may be obtained as achieved by the present invention by varying the concentration, treatment time, etc. Accordingly, Leitao '295 fails to disclose all claimed features of instantly pending claim 1. In this regard, anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949 (Fed. Cir. 1990) (citing *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Here, because of the lack of disclosure of all features as instantly claimed, the rejection in view of Leitao '295 is overcome. Further, by virtue of their dependency on amended claim 1, claims 2 and 11 are also patentable. Reconsideration and withdrawal of this rejection are respectfully requested.

Instantly Pending Claim 13 and Claims Dependent Thereon

Applicants respectfully refer the Examiner to claim 13 as shown herein. In this regard, this rejection has been instantly overcome as the subject matter of claim 15 is not at issue. Thus, withdrawal of this rejection is respectfully requested. Applicants add the following points of distinction.

Claim 13 as pending specifies that the microroughness has a root-mean-square roughness ( $R_q$  and/or  $S_q$ ) of  $\leq 250$  nm. In contrast, the cited Leitao '295 reference discloses an average peak distance between 10 and 1000 nm and an average depth between about 20 nm and about 500 nm. Therefore, Leitao '295 fails to disclose the instantly claimed peak width at half the pore depth, which according to the invention, should be from 15 to 150% of the pore diameter. Hence, Leitao '295 fails to disclose all recited features of pending claim 13 (even before incorporating the subject matter of claim 15). Furthermore, Leitao '295 does not specify that the root-mean-square roughness ( $R_q$  and/or  $S_q$ ) should be  $\leq 250$  nm. Thus, Leitao '295 fails to disclose several features of claim 13.

Accordingly, Leitao '295 fails to disclose all instantly claimed features and under *Robertson, supra*, this rejection has been overcome. Furthermore, by virtue of their dependency on amended claim 13, the rejection of claims 14 and 17-20 has also been overcome. Reconsideration and withdrawal of this rejection is respectfully requested.

***Issues under 35 U.S.C. § 103(a)***

Claims 1, 3, 6-10, 15 and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Leitao '295 in view of Hama *et al.* (U.S. Patent No. 4,818,559; hereinafter

"Hama '559") (see paragraphs 4-5 of the Office Action). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested. Claims 1 and 13 are independent claims, and are thus discussed separately below.

Claim 1 and Claims Dependent Thereon

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467. Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Here, Applicants respectfully submit that the Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue. Further, Applicants respectfully submit that there is no proper rationale in combining the disclosures of Leitao '295 and Hama '559 to achieve the present invention.

Applicants note the problems with Leitao '295 as discussed above. For instance, Leitao '295 fails to disclose any details of a method wherein a surface roughness may be obtained as achieved by the present invention by varying the concentration, treatment time, etc.

Also as explained above, claim 1 as instantly amended includes the features of claim 6. In other words, the present invention is directed to a desired microroughness being provided by treating the metallic implant surface with an aqueous solution of hydrofluoric acid, wherein the concentration of the hydrofluoric acid is less than 0.5 M. Still, according to the Examiner, it would have been obvious to the skilled person to make an implant with a surface roughness with the claimed concentration of hydrofluoric acid, as well as the claimed period of time of treating/etching, based on the disclosures of Leitao '295 and Hama '559. Applicants respectfully disagree.

The etching conditions are important in achieving the desired microroughness, i.e., a microroughness comprising pores and peaks having a pore diameter of  $\leq 1 \mu\text{m}$ , a pore depth of  $\leq 500 \text{ nm}$ , and a peak width, at half the pore depth, of from 15 to 150% of the pore diameter. Etching with hydrofluoric acid at different concentrations may result in very different roughnesses on an implant surface. In fact, the secondary reference of Hama '559 describes that its treatment with hydrofluoric acid results in large surface irregularities, i.e., in the range of  $15 \mu\text{m}$  to  $100 \mu\text{m}$  (see, e.g., column 3, lines 30-32 as well claim 1 spanning columns 5-6 of Hama '559). This range corresponds to the definition of a macroroughness given in paragraph [0037] of the present application. Referring to, e.g., WO 95/17217, which is mentioned in the background description of the present application, treatment with hydrofluoric acid results in an implant surface which is unaffected and wherein no significant etching occurs. Neither Leitao '295 nor Hama '559 provide such guidance to this microroughness to one of ordinary skill in the art. Accordingly, Applicants respectfully submit that the cited combination of Leitao '295 and Hama '559 is improper.

Applicants advise that any cited reference used for a rejection under 35 U.S.C. § 103(a) must be considered in its entirety, *i.e.*, as a whole, including those portions that would lead away from a claimed invention. See *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Here, Hama '559 actually teaches away from the presently claimed invention in describing HF treatment results in macroroughness, and not microroughness.

Further, there is no proper reason or rationale to combine Leitao '295, which lacks disclosure of the subject matter of claim 6, with Hama '559 which teaches large surface irregularities. *Graham; KSR Int'l; supra*. The present invention would not even be achieved based on such disclosures of these references. Though the Examiner in the Office Action refers to the ranges as being "well within the skill of an artisan," Applicants respectfully submit that the proper rationale is still lacking given the actual teachings of the cited references as explained above.

Hence, it cannot be considered obvious for a person of ordinary skill in the art to provide an implant with the specific surface roughness as instantly claimed (see claim 1 herein), by treating the implant surface with an aqueous solution of hydrofluoric acid, wherein the concentration of the hydrofluoric acid is less than 0.5 M. The primary reference of Leitao '295 does not even disclose the instantly claimed hydrofluoric acid concentration. Hama '559 does not cure the deficiencies of Leitao '295 as this secondary reference describes that its treatment with hydrofluoric acid results in large surface irregularities, *i.e.*, in the range of 15  $\mu\text{m}$  to 100  $\mu\text{m}$ .

Accordingly, the rejection of claim 1 has been overcome. Further, by virtue of their dependency on amended claim 1, the rejection of claims 3 and 7-10 has also been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim 13 and Claims Dependent Thereon

Regarding pending claim 13, this claim is directed to the following microroughness parameters:

- (1) a pore diameter of  $\leq 1 \mu\text{m}$ ;
- (2) a pore depth of  $\leq 500 \text{ nm}$ ;
- (3) a peak width, at half the pore depth, of from 15 to 150% of the pore diameter; and
- (4) a root-mean-square roughness ( $R_q$  and/or  $S_q$ ) of  $\leq 250 \text{ nm}$ .

As explained in Applicants' specification, it has been shown that surprisingly good biocompatibility results are obtained for an implant, implanted into bone tissue are achieved with an implant having the above mentioned microroughness. Both an improved rate of attachment, and a stronger bond between the implant surface and the bone tissue are obtained. Thus, the fine microroughness improves the osseointegration process (see paragraph [0021] of the published application).

Applicants note the problems with Leitao '295 as discussed above. For instance, Leitao '295 fails to disclose the instantly claimed peak width at half the pore depth, which according to the invention, should be from 15 to 150% of the pore diameter. Thus, though Leitao '295 does disclose an implant having a specific microroughness, Leitao '295 fails to disclose at least features (3) and (4) as instantly claimed.



Hama '559 cannot be properly combined with Leitao '295. The cited secondary reference of Hama '559 discloses a surface macroroughness of 15 to 100  $\mu\text{m}$  (see column 3, lines 30-32 and its claim 1). Accordingly, as explained above with respect to pending claim 1, Hama '559 teaches away from the presently claimed invention since this secondary reference teaches, e.g., macroroughness.

Further, there is no proper reason or rationale to combine Leitao '295, which lacks disclosure of the subject matter of claim 6, with Hama '559 which teaches large surface irregularities. *Graham; KSR Int'l; supra*. The present invention would not even be achieved, wherein the skilled person would not arrive at the present invention based on the disclosures of Leitao '295 and Hama '559.

Accordingly, the rejection of claim 13 has been overcome. The rejection of claim 16 has also been overcome for the same reasons stated above as this claim depends on claim 13. Reconsideration and withdrawal of this rejection are respectfully requested.

### ***Conclusion***

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

Application No. 10/519,495

Art Unit 3732


Reply to Office Action of May 14, 2008

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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.147; particularly, extension of time fees.

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Respectfully submitted,

By 

Craig A. McRobbie

Registration No.: 42,874

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road, Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant